

IN THE DRAWINGS

Applicants have added the element numbers 303, 304 and 305 to Fig. 3 to reference the protrusions mentioned by the Examiner. Applicants are enclosing a replacement drawing sheet with this Response.

REMARKS

At the time the current Official Action was mailed, the Examiner rejected claims 1-20. The prior art of record has been carefully studied, and Applicants have amended claims 1-20 and added new claims 21-48 in an effort to focus the various claims on certain aspects of the present invention that are believed to clearly distinguish over the prior art of record. Although Applicants will generally address the Examiner's rejections below, it should be understood that the reorganization of the claimed subject matter was not made with regard to the Examiner's specific rejections, so the rejections do not necessarily apply to the claims as amended. Applicants apologize for any possible confusion caused by these amendments, but it is believed that the reorganization of the claimed subject matter will facilitate the orderly prosecution of the present application. Reconsideration of the application in view of the remarks set forth below is respectfully requested.

Objections to the Drawings

The Examiner objected to the drawings, specifically stating that "the protrusions (flexible flap) must be shown or the feature(s) cancelled from the claim(s)."

Applicants respectfully disagree with the Examiner's objection. Indeed, the protrusions, including the flexible flap, are clearly illustrated in Figs. 2-5. Because the protrusions are primarily discussed in paragraph [0026] with reference to Fig. 3, Applicants have amended paragraph [0026] and Fig. 3 to clearly denote the protrusions 303, 304, and 305. In accordance with 37 C.F.R. § 1.121(d), Fig. 3 has been resubmitted in its amended form with the label "Replacement Sheet" in the top margin.

In view of the amendments and remarks set forth above, Applicants respectfully submit that the drawings as originally filed clearly illustrated the claimed protrusions. Accordingly, Applicants respectfully request withdrawal of the Examiner's objection and acceptance of amended Fig. 3.

Resections under 35 U.S.C. § 103

The Examiner rejected claims 1-6 and 13-15 under 35 U.S.C. § 103(a) as being unpatentable over Brain (U.S. 5,878,745) in view of Pagan (US 6,003,514). Specifically, the Examiner stated:

Claims 1-6 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (US 5878745) in view of Pagan (US 6003514). Brain discloses a laryngeal airway device, comprising an airway tube 11 having a proximal end and a distal end, said airway tube having an internal passage in the airway tube wall as shown in Figure 1. In addition, Brain discloses a dome 13 having an inlet and an outlet, said dome connected at its inlet with said distal end of said airway tube; an annular spoon-shaped inflatable cuff 18 connected with the periphery of said outlet of said dome; a cuff inflation line 19 having a proximal end and a distal end, wherein said cuff inflation line 19 is configured to be in fluid communication with the internal space of said cuff; and an aperture 14 having multiple lobes formed in said dome; said aperture configured to be in fluid communication with the proximal end of said airway tube. A lobe is defined as a "rounded projection" (dictionary.com). Therefore, the top and bottom rounded sections of 14 can each be defined as separate lobes of the aperture. However, Brain doesn't explicitly disclose the dome as having a plurality of protrusions forming said aperture, and wherein one of said protrusions is configured to prevent the obstruction of said aperture by a patient's epiglottis. Pagan discloses a laryngeal airway device with an aperture having multiple lobes (34 and 35) and a plurality of protrusions (31 and 32) forming said aperture, and wherein one of said protrusions is configured to prevent the obstruction of said aperture by a patient's epiglottis (column 1, lines 34-38). Pagan continues to teach the protrusions 31/32 comprising a flexible flap. Therefore, it would have been obvious to a person with ordinary skill in the art at the time of the invention to modify Brain with the protrusions taught by Pagan in order to deflect the epiglottis during the insertion of

an airway device into patient thereby preventing the epiglottis from entering the air passage.

Office Action, Pages 3 and 4.

Applicants respectfully traverse this rejection. The burden of establishing *a prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish *a prima facie* case, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985).

The Brain '745 reference, the Pagan reference, and the remainder of the prior art of record have been carefully studied, and Applicants respectfully submit that independent claims 1 and 13 recite subject matter that clearly distinguishes over the prior art of record. In regard to claim 1, there is recited "a plurality of protrusions extending only partially into the aperture, and wherein one of the protrusions is relatively flexible as compared to the remainder of the plurality of protrusions." None of the prior art of record, taken alone or in combination, discloses or suggests this feature. To the extent that the Brain '745 discloses protrusions extending across the aperture 14, it is clear that such protrusions extend completely across the aperture. See, e.g., Brain' 745,

Fig. 3. Furthermore, there is no indication whatsoever, that one of the "protrusions" is relatively flexible as compared to any other protrusions. Similarly, the Pagan reference fails to disclose that one of the flaps 31 and 32 is relatively flexible as compared to the other. The remainder of the art of record is similarly ineffectual in this regard. Therefore, none of the prior art of record anticipates or renders obvious the subject matter set forth in independent claim 1. As a result, Applicants respectfully request withdrawal of the Examiner's rejection and allowance of claims 1-12.

In regard to independent claim 13, there is recited a "cuff inflation line extending through the protruding dome tip." Applicants note that the Examiner did not expressly describe the manner in which the cited references are alleged to disclose or suggest the protruding dome tip as set forth in independent claim 13. However, the Examiner did state the following in regard to dependent claims 6, 14, and 15:

As for claim 6, Brain discloses a protruding dome tip 40 connected with the distal end of said outlet of said dome 13, said protruding dome tip's distal end being located in and in fluid communication with said internal space of said cuff 18 as shown in Figure 3.

As for claim 14, the protruding dome tip 40 comprises a slit at its distal end, so as to cause said protruding dome tip to maintain fluid communication with the internal space of said cuff 18 when said cuff is adjacent to said distal end of said protruding dome tip 40 (see Figure 3 and Figure below).

As for claim 15, Brain discloses the protruding dome tip 40 which is part of the dome 13 is less elastic than the cuff 18 so as to prevent said cuff from folding back on itself when said device is inserted into a patient (column 4, lines 1-18).

Office Action, Pages 5 and 6.

Applicants are somewhat confused by the Examiner's rejection, because element 40 in the Brain `745 reference is simply described as a "distal location" at which the tube 26 is adhesively sealed to the ring 18. Brain `745, column 6, lines 2-9. Indeed, to the extent that the Examiner has redrafted Fig. 3 of the Brain `745 reference to re-designate the element 40 as a "slit," it seems quite clear that a "slit" (a long narrow cut or opening) is not a structural feature and thus, cannot be equated to the claimed "protruding dome tip." However, to the extent that the Examiner is actually relying upon the tube 26 which apparently extends through the "slit" 40, Applicants respectfully draw the Examiner's attention to Fig. 6 of the Brain `745 reference, which clearly shows that the tube 26 extends completely through the cuff 18 such that the distal-end opening 43 of the tube .26 establishes an "evacuation connection" to the upper sphincteral region of the esophagus through the evacuation tube 23 that is coupled to the tube 26 to enable evacuation and waste collection. Brain `745, column 7, lines 6-25. In other words, the tube 26 is clearly in fluid communication with the patient, not with the internal space of the inflation ring 18. Therefore, the Brain `745 reference clearly does not disclose or suggest the subject matter of independent claim 13 which recites that the protruding dome tip that has a cuff inflation line in fluid communication with the internal space of the cuff. As a result, Applicants respectfully submit that claims 13-15 are allowable over the cited art, and Applicants respectfully request withdrawal of the Examiner's rejection and allowance of claims 13-15.

The Examiner rejected claim 7 under 35 U.S.C. 103(a) as being unpatentable over Brain `745 and Pagan in view of Brain (US 6439232). Applicants respectfully traverse this rejection. As discussed above, the Brain `745 reference and the Pagan reference do not disclose or suggest the subject matter set forth in independent claim 1. The Brain `858 reference fails to cure the

deficiencies of the primary references. Specifically, the Brain '858 reference discloses a single deflectable bar 20 that extends *across* the air passage 17, where the end 23 of the bar 20 is adapted to rest within a stop or recess 24. Brain '858, Figs. 3 and 7; column 6, line 5 - column 7, line 27. Therefore, the Brain '858 reference does not disclose or suggest "a plurality of protrusions extending only partially into the aperture, and wherein one of the protrusions is relatively flexible as compared to the remainder of the protrusions," as set forth in independent claim 1 from which claim 7 indirectly depends. Accordingly, Applicants respectfully request withdrawal of the Examiner's rejection and allowance of claim 7.

The Examiner rejected claims 8-10, 16, 17, and 18 under 35 U.S.C. 103(a) as being unpatentable over Brain in view of Pagan. Specifically, the Examiner stated:

Brain discloses the outlet of the dome further comprising a tray portion 33, and said cuff 18 further comprises a channel on the inner surface of the annular shaped cuff, said channel 38 being connected with the periphery of aid outlet of said dome at said tray portion 33 (Figure 4).

Brain continues to disclose the cuffs outer surface as being formed in the absence of external protrusions, said cuff 18 further comprising a mold extraction orifice 27 at its distal end formed on an internal surface of said cuff, and wherein said cuff inflation line 19 is configured to be in fluid communication with the internal space of said cuff at an opening comprising said mold extraction orifice as shown in Figures 1 and 2. Although Brain and Pagan haven't explicitly taught a removable connector connected with said proximal end of said airway tube. Applicant has disclosed prior art in Figure 1 of the Specification that teaches the connector 7 as claimed.

Office Action, Pages 6 and 7.

Applicants respectfully traverse this rejection. Although the Examiner did not specifically indicate which Brain reference was being relied upon, Applicants assume that the Examiner is relying upon the Brain `745 in this rejection. Accordingly, claims 8-10, which depend from independent claim 1, are believed to be allowable for the reasons set forth above. Therefore, Applicants respectfully request withdrawal of the Examiner's rejection and allowance of dependent claims 8-10.

In regard to independent claim 16, Applicants note that claim 16 recites "at least a portion of the cuff inflation line being formed along a portion of the airway tube opposite the outlet of the dome." As described by way of example in paragraph [0030] of the present application, Fig. 7 discloses that the air inflation line passes through a passage 102 in the tube 100 that is on the side of the airway tube opposite the outlet of the dome 300. Again, the prior art of record has been carefully reviewed, and none of the references, taken either alone or in combination, disclose or suggest this feature. Indeed, Fig. 1 of the Brain `745 patent discloses an inflation line 19 running along the airway tube 11 on the same side as the outlet of the dome, and Fig. 1 of the Pagan reference similarly discloses an inflation tube 3 running along the airway tube 1 on the same side as the outlet of the dome 13. Therefore, Applicants respectfully submit that independent claim 16, as well as new dependent claim 23, are allowable over the prior art of record.

In regard to independent claim 17, the Examiner has, without explanation, apparently equated the "blunted distal end 27 of ring 18" with the claimed "mold extraction orifice." See Brain `745, column 4, lines 19-22; Fig. 2. Because "the blunted distal end 27" of the Brain `745

reference bears no resemblance to a "mold extraction orifice," such as the exemplary mold extraction orifice 204 disclosed in the present application in paragraph [0029] and in Fig. 6, Applicants respectfully submit that the Examiner has failed to demonstrate *a prima facie* case of obviousness with regard to the subject matter set forth in independent claim 17. Therefore, Applicants respectfully request withdrawal of the Examiner's rejection and allowance of claim 17.

In regard to independent claim 18, the Examiner admitted that the cited art does not explicitly teach a removable connector connected with the proximal end of the airway tube. Nevertheless, the Examiner suggested that Applicants have disclosed prior art in Fig. 1 that teaches such a connector 7 as claimed. Here, the Examiner is clearly in error regarding the disclosure set forth with regard to Fig. 1 of the present application. In contrast to the Examiner's assertion, the present application describes the connector 7 as being "securely attached" to the airway tube. Application, p. 2, lines 6-7. Furthermore, the present application states:

At its proximal end the tube 100 is connected with a removable connector 104. In contrast to the more common way of adhesively attaching the connector with the tube, the connector 104 is press fitted into place and not adhesively adhered with the tube 100. In this manner, the connector 104 is easily removable to allow the insertion of another device, such as for example an endotracheal tube or bronchoscope through the airway tube 100.

Application, p. 4, lines 11-16.

In view of the fact that the present application clearly does not disclose or suggest that the prior art described in relation to Figure 1 teaches a removable connector, Applicants respectfully request withdrawal of the Examiner's rejection and allowance of independent claim 18.

The Examiner rejected claims 11, 12, 19, and 20 under 35 U.S.C. 103(a) as being unpatentable over Brain and Pagan in view of Neame et al. (US 5979445). Specifically, the Examiner stated:

Brain discloses a cuff inflation line 19 that is configured to be in fluid communication with the internal space of said cuff 18 at a distal end of said cuff. However, Brain and Pagan don't explicitly disclose an inflation line insertion point offset distally from said proximal end of said airway tube, said insertion point being the proximal end and integral with said internal passage. However, Neame et al. teach a laryngeal device with an inflation line insertion point (where 3 meets 1) offset distally from said proximal end of said airway tube 1, said insertion point being the proximal end and integral 2 with said internal passage. A portion of the length of said cuff inflation line 2 is placed in said passage 1 as shown in Figure 1.

Office Action, Page 8.

Applicants respectfully traverse this rejection. Again, Applicants assume that the Brain reference being relied upon by the Examiner is the '745 reference. Accordingly, in regard to dependent claims 11 and 12, Applicants respectfully assert that these claims are allowable for the same reasons as set forth with regard to independent claim 1. Furthermore, the Neame reference discloses no protrusions whatsoever in relation to the aperture 26, so the Neame clearly fails to cure the deficiencies of the primary references. Accordingly, Applicants respectfully request withdrawal of the Examiner's rejection and allowance of dependent claims 11 and 12.

In regard to independent claim 19, a review of the prior art of record indicates that none of the cited references, taken either alone or in combination, disclose or suggest a cuff inflation line "configured to be in fluid communication with an internal space of the cuff at a

distal end of the cuff’ as claimed. Emphasis added. Indeed, the prior art of record appears to disclose cuff inflation lines that are in fluid communication at the proximal end of the respective cuffs. Accordingly, the subject matter of claim 19 clearly distinguishes over the prior art of record, and Applicants respectfully request withdrawal of the Examiner's rejection and allowance of claims 19 and 20.

In view of the amendments and remarks discussed above, Applicants respectfully submit that claims 1-23 clearly distinguish over the prior art of record. Therefore, Applicants respectfully request withdrawal of all outstanding rejections and allowance of claims 1-23.

New Claims


Applicants have added new independent claims 24, 26, 27, 39, 42 and 44. New independent claim 24 recites "no more than one flexible epiglottis barrier ...extending only partially into the aperture" at the outlet of the dome. New independent claim 26 recites "at least three protrusions attached to the outlet of the dome, the at least three protrusions radially offset from one another and extending only partially into the aperture." New independent claims 24 and 44 recite a cuff that “inflates from its distal end.” New independent claim 39 recites a protruding dome tip “in fluid communication with the distal end of the inflation line and the inside of the cuff.” New independent claim 42 recites that “at least a portion of the line runs from the dome inlet to the dome outlet.” Again, none of the prior art of record, taken either alone or in combination, discloses or suggests the subject matter set forth in the new independent claims. Accordingly, Applicants respectfully request allowance of new claims 21-48.

Conclusion

In view of the remarks set forth above, Applicant respectfully requests reconsideration of the Examiner's rejections and allowance of all pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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